DC | HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

HEALTH AWARENESS TESTING
REQUIRED DOCUMENTATION AND PROCEDURES

REQUESTS MUST BE RECEIVED 14 DAYS PRIOR TO THE TESTING EVENT

NOTIFICATION OF CANCELLATIONS MUST BE RECEIVED WITHIN 48 HOURS

To perform Health Awareness testing in the District of Columbia, you will need Federal Clinical Laboratory Improvement Amendments (CLIA) certification. Health Awareness testing includes waived lipid testing, glucose, and hemoglobin A1C. Not all laboratory tests are considered waived, and paying special attention to the package inserts for reagents, test kits, test strips, and instrument manuals is required and must be maintained. A copy of the CLIA permit must be posted at the location where testing is performed. An unannounced survey may be performed on the day of the screening event.

If you are performing waived COVID-19 testing, you are required to apply for the Communicable and Reportable Disease license. ALL COVID TEST RESULTS MUST BE REPORTED TO DC HEALTH.

Before the test system may be used at a temporary or mobile laboratory test site, analyze two levels of quality control materials, and perform maintenance procedures as required by the manufacturer.

Email the following documentation to: michele.tallent@dc.gov

Submit a copy of the following as written in the Standard Operating Procedure Manual:

- **Written SOPM'S of all waived tests performed**
- **Quality control and maintenance documentation written procedures for all tests**
- **Testing personnel training/competency written procedures**
- **Copy of all testing personnel training/competency**
- **Occupational Safety and Health Administration (OSHA) written regulations for occupational exposure to bloodborne pathogens**
- **A copy of the package inserts of all test kits**

Submit a copy of worksheets used for documentation of laboratory activities as part of the written SOPM:

- **Quality control worksheet including the lot number and expiration date**
- **Final report form that is given to the participant (include name, address and phone number of the laboratory)**
- **Consent form for participant to sign**

Once the event is complete, all quality controls and maintenance procedures performed on the day of the screening event must be forwarded to our office within 14 days. Ten copies of patient test records must also be submitted within 14 days.

HEALTH AWARENESS TESTING

FORM MUST BE POSTED AT SCREENING EVENT

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E-MAIL HEALTH AWARENESS TESTING SITE REQUEST FORM TO: michele.tallent@dc.gov

DATE OF REQUEST: _____

FEDERAL CLIA NUMBER OF LABORATORY PERFORMING THE TESTING: _____
(PROVIDE A COPY OF CERTIFICATION WITH SUBMITTED REQUIRED DOCUMENTATION)

[ ] THIS IS AN INITIAL REQUEST. (IF THIS IS AN INITIAL REQUEST, SUBMIT A COPY OF THE DIRECTOR'S LICENSE WITH THIS FORM)

DATE AND TIME OF SCREENING EVENT: _____

COMPLETE NAME AND ADDRESS OF SCREENING EVENT, CONTACT PERSON NAME AND PHONE NUMBER:

_____

_____

TESTS TO BE PERFORMED:

_____

_____

NAME(S) OF TESTING PERSON(S):

_____

EMAIL ADDRESS TO WHICH THE SITE APPROVAL CAN BE FORWARDED AFTER REVIEW OF SUBMITTED DOCUMENTS:

_____

LABORATORY DIRECTOR SIGNATURE/DATE: _____

Office Use: Approved ☐ **Not Approved** ☐

Code of the District of Columbia
§ 44–202. License requirements for clinical laboratories
§ 44–207. Inspections

10/2021